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14. ABSTRACT

Purpose: The purpose of this study was 1) to explore the utility of a female urinary diversion device (FUDD) as a self-care measure for female urination in the deployment environment, and 2) determine if there are differences in self-reported urinary symptoms between an intervention group and control group of deployed military women (MW).

Design: This feasibility study design consisted of a randomized controlled trial [intervention group (IG) and control group (CG)] with repeated measures.

Methods: Both groups completed a "*Predeployment Baseline Assessment Form"*.. The IG received two FUDDs and instructions. They completed the "*Urination and FUDD Use during Deployment Survey"* at 3 and 6 months during deployment. The CG completed the "*Urination during Deployment Survey*" at 3 and 6 months during deployment.

Sample: MW (n = 94) deployed for ≥ 6 months to austere locations in support of Operation Enduring Freedom (OEF) were recruited from an SRC. They were randomly assigned to the IG
(n = 61) or CG (n = 33). Of the 61 military women randomized to the IG, twenty-two completed the three-month questionnaire and twenty-six completed the six-month questionnaire. Of the 33 individuals randomized to the CG, seven completed the three-month questionnaire and six completed the six-month questionnaire.

Analysis: Descriptive and content analyses provided support for the FUDD's utility in austere environments. Clinically significant differences in urinary symptoms between groups were determined. Results demonstrated the FUDD was easy to use, store, and carry. The CG group reported that they would have liked to have the FUDD. Both groups recommended it and reported there were many opportunities for a FUDD due to unsanitary and challenging conditions.

Implications for Military Nursing: This research provides scientifically based support for the FUDD's feasibility for MW in austere settings and clinical support for the FUDD as a self-care measure.

15. SUBJECT TERMS
female urinary diversion device, deployed military women's health, genitourinary health in deployed women, urination in austere environments

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Abstract

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Searchable key words: female urinary diversion device, deployed military women's health, genitourinary health in deployed women, urination in austere environments

TSNRP Research Priorities that Study or Project Addresses

Primary Priority

Force Health Protection:	☒ Fit and ready force ☐ Deploy with and care for the warrior ☐ Care for all entrusted to our care
Nursing Competencies and Practice:	☐ Patient outcomes ☐ Quality and safety ☐ Translate research into practice/evidence-based practice ☐ Clinical excellence ☐ Knowledge management ☐ Education and training
Leadership, Ethics, and Mentoring:	☐ Health policy ☐ Recruitment and retention ☐ Preparing tomorrow's leaders ☐ Care of the caregiver
Other:	☐

Secondary Priority

Force Health Protection:	☐ Fit and ready force ☐ Deploy with and care for the warrior ☐ Care for all entrusted to our care
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Leadership, Ethics, and Mentoring:	☐ Health policy ☐ Recruitment and retention ☐ Preparing tomorrow's leaders ☐ Care of the caregiver
Other:	☒ Health promotion and risk reduction

Progress Toward Achievement of Specific Aims of the Study or Project
Findings related to each specific aim, research or study questions, and/or hypothesis:

The Sample:

Demographic characteristics of the participants are provided in Table 1 based on their group assignment. There were 94 Military Women (MW) respondents. All respondents were in the Army and on active duty. Of the total respondents, 35% (n = 33) were randomized to the control group (CG), while 65% (n = 61) were randomized to the group that received a FUDD (IG) shown in Figure 1. The majority of both the IG and CG were Non-Hispanic Whites, 57% and 45% respectively. The IG and CG had similar mean ages. The majority of all participants were college educated (IG =92%: CG=94%).

Where a p-value could be calculated (using $\alpha < 0.05$), there were no significant differences between the IG and CG pre-deployment. As can be seen in Table 2, similar urinary symptoms were experienced by both groups, with blood in urine and the urge to urinate frequently being the two most cited issues in both groups. The FUDD group also appeared to experience more Urinary Tract Infections (UTIs) pre-deployment, but due to the small number of individuals diagnosed, it was not possible to determine whether this was a significant difference. The prevalence of UTIs was small at 7.4%. A much larger sample would be needed to detect a difference between groups.

Specific Aim 1: To determine the feasibility (utility effects: convenience, frequency, and ease of use) of the FUDD as a self-care measure for urination among MW in a deployment environment.

This specific aim was addressed after the IG completed the 3 month and/or 6 month surveys. The survey questions were designed to assess the utility effects, convenience, frequency, and ease of use of the FUDD device. There were 94 enrolled participants who were randomized according to their assigned military location (north or south) to either the IG (n=61) or CG (n=33). The IG completed baseline surveys and each MW received two FUDD devices (with an instruction card) along with a hands-on demonstration on how to use it per protocol. After the MW deployed, the 3 and 6 month surveys were emailed by investigators, completed by participants, and collected through Survey Monkey. Although the MW had the option of mailing the survey in a preaddressed stamped envelope, no respondents chose this response type. Of the 61 MW in the IG, only 22 completed the three-month questionnaire and 26 completed the 6 month questionnaire. Among those that completed surveys, several factors influenced whether or not they used the FUDD (see Table 3). More than half (55%, n = 12 at 3 months and 65%, n = 17 at 6 months) of respondents with a FUDD used it regularly. Unsanitary toilet facilities, long distance to toilets, and not wanting to leave the barracks to use the bathroom at night were the most common reasons cited for using the FUDD. Data showed that the FUDDs were most commonly used in the individual's living quarters or when using the bathroom outside. Nearly 17% (n = 4) reported in the comment section that they "did not want to go outside the barracks to urinate at night." Furthermore, 83% (n = 10) of respondents at 3 months and 94% (n = 16) at 6 months were able to rinse their FUDD to clean it regularly.

Overall, respondents were satisfied with the FUDD and most respondents would recommend the FUDD to a friend (see Table 3). Nearly all respondents, 95%, felt that the FUDD should be provided to all military women who are deploying. Furthermore, more women found

pre-deployment instructions about the FUDD care and use more helpful than the instruction card. On the other hand, when adequate toilette facilities were available, the FUDDs were not used regularly. When no toilet facilities were available, the majority of those in the FUDD group (78%, n = 14) at three months and (95%, n = 18) at six months used their FUDD (see Table 4). Also, one individual in the control group used a FUDD when no toilette facilities were available, although one was not given to them through this study. No individuals in the study were unable to work due to urinary symptoms.

One FUDD issue reported by approximately 17% (n = 4) at 3 months and 47% (n = 8) at 6 months was that it could be difficult to remove the device from trousers; it was messy and difficult to use. Another issue reported by 13% (n = 3) at 3 months and 18% (n = 47%) at 6 months was that it could be messy/leaky. Those women that received the FUDD generally found it easy to store, use, clean, and transport. All individuals found the FUDD convenient. Further statistical tests could not be conducted with the data due to small sample sizes. However, there did not appear to be major differences in responses at 3 months compared to 6 months.

Specific Aim 2: To compare self-reported urinary symptoms and UTIs between MW in the FUDD IG and MW in the standard pre deployment SRC program group (CG) at 3 months and at 6 months during deployment.

Control and FUDD Group Comparisons

This specific aim was addressed after subjects completed the baseline, 3 month, and/or 6 month surveys. The survey questions were designed to assess and compare participant reported UTI symptoms and diagnoses between groups. All enrolled participants in both the IG and CG completed baseline surveys. Unfortunately, of the 33 individuals randomized to the CG, only 7 completed the 3 month questionnaire and 6 completed the 6 month questionnaire. The study statisticians recommended that due to the small sample size and high attrition rates, descriptive analyses should only be performed on those who completed all three surveys (baseline, 3 month, and 6 month).

Urinary symptoms and treatment between the IG and the CG at 3 months and 6 months were analyzed (see Table 5). At 3 months, 82% (n = 18) of those in the IG did not experience urinary problems compared to the 57% (n = 4) in the CG. The results were similar at 6 months, 73% (n = 19) vs. 50% (n = 3) respectively. It is difficult to compare urinary symptoms between groups because the control group was so small at 3 and 6 months. No statistical comparison could be made over time between the IG and CG groups because of the small CG sample size.

Relationship of current findings to previous findings:

As reported in earlier studies, austere environments pose unique female genitourinary (GU) concerns.[1,2] Earlier studies reported that field urination requires MW to not only undress sufficiently to prevent soiling clothes, but to squat and then redress. This compromised position leaves her exposed to those around her, including the enemy. Seeking shelter or privacy is not always possible. Current studies showed that MW reported that there were no toilets available during certain conditions and in some of austere environments of deployment. Results from the current study revealed that both groups reported experiencing situations where there were no toilet facilities available. Interestingly, the IG reported experiencing more situations where there were no toilet facilities at 3 months (82%, n = 18) and 6 months (73%, n = 19) than the CG (see Table 5).

Even when toilets are available, many are unsanitary, preventing the use of the sitting position to urinate.[3,4,5] This study supported previous findings regarding privacy, safety, and difficult conditions when urinating during deployment. At 3 months, the IG reported the factors that influenced them to use the FUDD were unsanitary toilets (33%, n = 4), lack of privacy (8%, n = 1), and that bathrooms were a long distance away (50%, n = 6) and/or would require them to go outside their barracks at night (33%, n = 4). The 6 month survey revealed the same factors: that toilets were unsanitary (59%, n = 10), not private (29%, n = 5), a long distance away (65%, n = 11), and required MW to go outside their barracks at night (53%, n = 9). Two MW added comments that they "did not feel safe leaving the barracks". Interestingly, there was an increased number of MW reporting this adverse condition from the 3 month to the 6 month survey. These findings demonstrate that many of the difficult austere conditions did not improve over time.

Previous studies reported the need for MW to undress and maneuver into awkward squatting positions to avoid seat contact.[9,6,7,8,9] This position is even more difficult in combat related settings due to additional field gear.[1] In the current study, the IG reported that they used the FUDD in their military vehicle, living quarters, outside, and inside a clean or dirty toilet facility (see Table 3). The majority of MW in the current study also reported an ease of using the FUDD for urinating when wearing added gear and equipment (see Table 2).

In an earlier study[3], 77.3% (650/841) of MW reported either holding urine or intentionally restricting fluids to limit urination. In the current study, both groups reported holding urine and urinating in a container or in a discrete place outside, but there was a higher percentage in the CG that used these unfavorable strategies more frequently (see Table 4). As demonstrated by study results from this FUDD study, the IG members with the FUDD were able to urinate under most conditions, rather than employing potentially unsafe strategies when toilet facilities were inconvenient, unsanitary, or unavailable.

Effect of problems or obstacles on the results:

1. Due to unforeseen circumstances related to LTC Steele's deployment (Dec 2012 – Jul 2013) and many difficulties and delays of Womack Army Medical Center's (WAMC) in-process requirements for the Project Director, Dr. Shawana Taylor (Sept 2012 - March 2013), recruitment was stymied.
2. Another obstacle was that the on-site PI and on-site AI had agreed to recruit and consent participants, but did not do so. My consultant (Dr. Ledbetter) and mentor (Dr. Yoder) both contacted the onsite PI and AI, offering to travel to Fort Bragg to recruit and consent potential participants from the site, but both officers stated that they did not need their help. This was not the case, as the two officers had not initiated the study methodology and thus no recruitment had taken place at all over a number of months. LTC Steele contacted the officers from Afghanistan but was told the same information; that the study was going well except that Dr. Taylor's in-processing activities were still not complete, so she was not authorized to conduct the study. The described obstacles were overcome when Dr. Taylor's in-processing activities were complete and she was then approved and to initiate recruitment and other study activities.
3. Due to the nature of the device used in this study and the study location (OEF), four IRBs were required prior to the beginning of data collection. This protracted delay lead to multiple revisions and reviews by all IRBs each time a change was required. The final approvals took more than a year.

4. Due to troop drawdown and withdrawal in OEF, data collection was suspended earlier than planned, contributing to recruitment of an inadequate sample size and reduction in collection of data. As a result, there was a major decline in study survey return. To address attrition, an amendment was administered that allowed participants to return their 6-month surveys through Survey Monkey® upon returning to Fort Bragg. Unfortunately, this change only provided a return of an additional three IG surveys and two CG surveys.

Limitations:

A major limitation was the small sample size (n = 94) that did not allow for the intended rigorous repeated measures statistical analyses. High attrition in the CG may have been due to not having the intervention. The uneven and small number in each group (IG = 61 & CG = 33) did not provide enough data to conduct repeated measures analyses. Instead, data were analyzed as descriptive data only. Lack of access to computers for data collection and the transient nature of a deployment also may have resulted in higher attrition rates in this study. Upon short answer analyses, it was apparent that a major factor for attrition in the CG was not being able to have the FUDD and thus they did not feel compelled to complete the surveys. In addition, findings from this study included only deployed MW in an austere environment, therefore the findings cannot be generalized.

Conclusion:

In conclusion, an inadequate sample size due to numerous recruitment difficulties, high attrition, and other obstacles diminished the statistical power to address the study aims. The planned rigorous analyses were changed to descriptive and short answer analyses. However, these results revealed clinically important and useful findings that can inform both future research and DOD policy regarding the FUDD as a self-care measure for urination among MW in a deployment environment.

The descriptive findings support a self-care measure that may assist MW to obtain and maintain optimum health and functioning as viable members of a "fit and ready force." Additionally, use of the FUDD may protect MW from being vulnerable in situations where they may be unintentionally exposed to the enemy. Additionally, for women who are assigned to mostly male units, the FUDD allows women to maintain their dignity by not having to expose themselves to their male counterparts for purposes of urination. The long-term objective of this study, to provide a low cost, portable, easy to use self-care measure, which has the potential to reduce the number of urinary symptoms and UTIs in deployed MW, thereby decreasing healthcare resources used for a preventable problem, was met.

Significance of Study or Project Results to Military Nursing

MW are being deployed to austere environments for field duties, training, combat support operations, disaster relief, and humanitarian missions. Unsanitary conditions, extreme temperatures, and difficult terrain often characterize these austere environments. In a recent study with deployed MW in Iraq, urinary symptoms were reported in 47% (189/372) of those surveyed.[6] It is imperative that MW's urination issues be addressed and risk factors for related health problems mitigated. UTIs persist among deployed MW because of the austere environment and lack of adequate sanitary toileting facilities. In order to obtain current information about UTIs during OIF/OEF, epidemiologists from the United States Army Center for Health Promotion and Preventive Medicine reviewed electronic outpatient, inpatient, and

medical evacuation records from OEF and OIF from January 1, 2006 through December 31, 2008 for diagnoses indicating UTIs. They reported that 3,556 female soldiers made 4,815 ambulatory visits for UTIs. These numbers represented nearly 10% of the MW ambulatory patient population and 2.5% of all electronically documented ambulatory visits among female soldiers. Approximately 22% of the MW had multiple visits for UTIs; 2% were diagnosed with acute pyelonephritis. Fifteen cases of UTIs were serious enough to warrant hospitalization and 4 required medical evacuations to higher levels of care.[5]

UTIs can cause pain and discomfort, which can interfere with mission duties, lead to lost work time, and affect the MW's overall well-being at a time when focus and concentration are critical. UTIs can be particularly problematic in austere environments where the number of health care services and medical resources are limited. With limited health care resources, many MW resort to self-treatments, which can lead to further complications that result in medical evacuations to combat support hospitals, or in some cases out of theater. Although the sample size for this study was small, the majority of MW in the FUDD group did not report urinary symptoms or UTIs. These results demonstrate how the use of the FUDD by MW in austere environments of deployment settings may assist in mitigating the impact the environment can have on urinary symptoms.

Study findings provided support for the use of an intervention that has the potential to alleviate MW's urination challenges and reduce risks for Genitourinary (GU) problems in the austere environment. Results from this study have expanded the body of military scientific knowledge and filled a gap regarding the feasibility of using the FUDD in austere environments. Future research recommendations include conducting more studies that will add understanding of the usability of the FUDD in different female populations and environments, such as military training, humanitarian missions, health relief missions, aboard ships, and aircraft. It is the opinion of this study's investigators that a control group is not necessary in future studies. This study demonstrated the benefits of having the FUDD outweigh the risks of not having the FUDD. In addition, the high CG attrition rate in this study and the unwillingness of CG participants to complete study requirements demonstrates the inherent difficulties of a control group for determining feasibility of the FUDD in different settings. Additionally, given the availability of the FUDD in the military logistical system, it would be unethical to withhold the device using a control group. Efforts to increase the retention of participants for the entire length of the study are important. Reducing the length of the surveys may help with this. Because there did not appear to be any real differences between the data collected at 3 and 6 months, collecting pre-deployment and 6 month data only would potentially answer the research questions.

Changes in Clinical Practice, Leadership, Management, Education, Policy, and/or Military Doctrine that Resulted from Study or Project

Although health experts have recommended that specialized educational sessions about female GU issues be added to pre-existing Solder Readiness Center (SRC) programs, most programs still do not address female GU issues.[7, 10,11,12,13] Because female health issues are not a mandatory part of most SRC programs, the responsibility for female health readiness continues to ultimately remain with MW themselves. This study demonstrated that the FUDD could be added to the SRC programs as a means to address female GU issues. In addition, the FUDD has now become part of another TSNRP study funded study that is addressing women's health issues in Army Airborne Corps MW at Fort Bragg, NC. The FUDD is included in a predeployment

female health hygiene toolkit issued prior to SRC attendance. This ongoing education program study (REAIM) supports the value of the FUDD.[14]

Because the FUDD is not a regularly issued item for females (although a military stock number is listed), few MW feel compelled to buy it. Without scientific support of studies like the current one, MW and medical providers alike will remain skeptical about the utility of the FUDD. This study provided scientifically based information regarding the FUDD as a self-care measure for women in the deployment setting. This research provided evidence for a self-care urination device that could decrease the difficulties and complications of urination for MW in the austere deployment setting and ultimately reduce risk factors for GU symptoms and UTIs.[12,15]

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Summary of Dissemination

Type of Dissemination	Citation	Date and Source of Approval for Public Release
Publications	Steele, N. & Yoder, L., (2013). Military Women's Urinary Patterns, Practices, and Complications in Deployment Settings. *Journal of Urologic Nursing,* 33(2): 61-71	Dec 05, 2012 - PAO: Womack Army Medical Center
Podium Presentations	Urinary Devices for Deployed Women, Nurse Research Conference, Bagram, Afghanistan, June 2013.	Womack Army Medical Center PAO; Dec 05 2012.
	Awarded Society of Urologic Nursing Literary Award for 2013; Society of Urology Nursing, Chicago IL.Nov 1013	Award acceptance for manuscript regarding women's health in the Military
	Internet Press Release: 3 April 2013: Deployment Health News . Army Researches Small Device to Reduce Female UTIs. Retrieved 20 June 2013 at http://www.army.mil/article/75918/	2 April 2013: Task Force Medical Afghanistan Public Affairs.
	Video Clip: 18 June 2013 The Office of the Surgeon General Women's Health Task Force: Female Urinary Diversion Device (Fudd) video 2013. Retrieved 20 June 2013 at http://youtu.be/JXRxjmifjO8	1 June 2013. The Office of the Surgeon General Public Affairs.

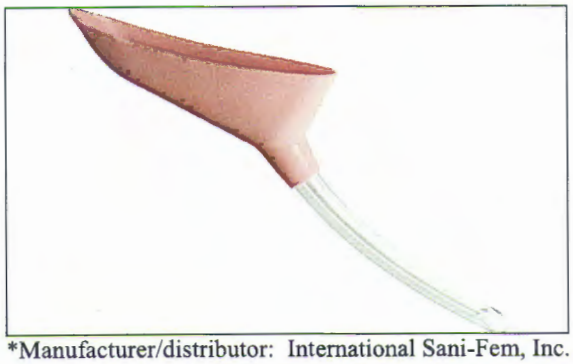
Reportable Outcomes

Reportable Outcome	Detailed Description
Applied for Patent	none
Issued a Patent	none
Developed a cell line	none
Developed a tissue or serum repository	none
Developed a data registry	none

Recruitment and Retention Table

Recruitment and Retention Aspect	Number	
Subjects Projected in Grant Application	90 (IG=45 & CG=45)	
Subjects Available	136	
Subjects Contacted or Reached by Approved Recruitment Method	94	
Subjects Screened	94	
Subjects Ineligible	0	
Subjects Refused	0	
Human Subjects Consented	94	
Subjects Intervention Group / Control or Sham Group	61	31
Intervention Group / Control or Sham Group Subjects Who Withdrew	0	0
Intervention Group / Control or Sham Group Subjects Who Completed Study	24	3
Intervention Group / Control or Sham Group Subjects With Complete Data	24	3
Intervention Group / Control or Sham Group Subjects With Incomplete Data	39	28

Figure 1. a.) FUDD photo



*Manufacturer/distributor: International Sani-Fem, Inc.
Freshette® retrieved from http://www.freshette.com/

Figure 2. FUDD placement digram and directions

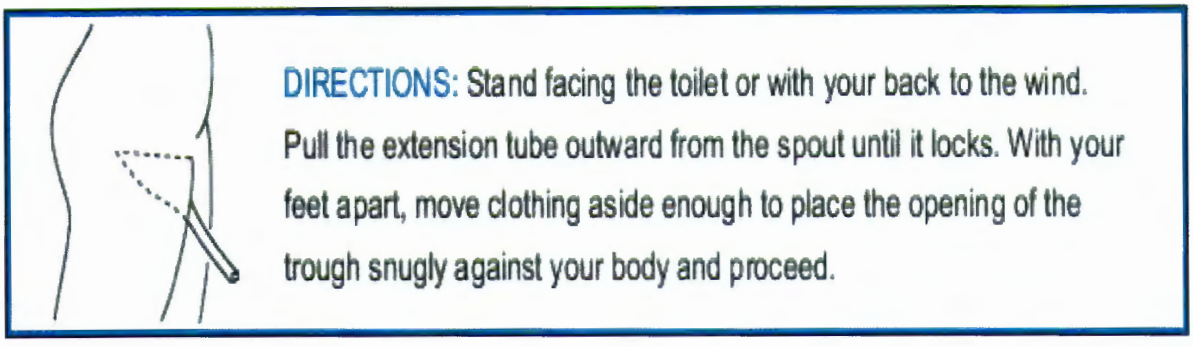


Table 1. Demographic Characteristics of the IG (FUDD) & CG Sample

Characteristic	N (%)	N (%)
Age (yrs)	27.96 ± 5.5	30.15 ± 6.8
Women	61(100)	33(100)
Race		
Non-Hispanic White	35(57)	15(45)
African American	9(15)	10(30)
Hispanic or Latino	7(11)	3(9)
Native Hawaiian or other Pacific Islander	1(2)	0
Asian	5(8)	2(6)
American Indian	0	1(3)
Other	4(7)	2(6)
Military Service or Civilian		
Air Force, n (%)	(0)	(0)
Army, n (%)	61(100)	33(100)
Marine, n (%)	(0)	(0)
Navy, n (%)	(0)	(0)
Service Component		
Active Duty	61(100)	33(100)
Years in Military	5.77 ± 4.8	7.51 ± 4.91
Officer	27(44.3)	16(48.5)
Enlisted	34(55.7)	17(51.5)
Education		
≤ High School/GED	5(7.6)	2(6)
Some College	11(18)	8(24.2)
2-yr College Degree	12(19.7)	5(15.2)
4-yr College Degree	22(36.1)	13(39.4)
Masters/PhD/Prof. Degree	11(7)	5(15.2)

Table 2. Urinary Symptoms for Past Year in Pre-deployment Groups

Urinary Symptoms in the Past Year			
	Control	**FUDD**	**P-Value**
N	33	61	
Foul Smelling	6 (18%)	12 (20%)	0.799
Cloudy	6 (18%)	15 (25%)	0.724
Blood	31 (94%)	53 (88%)	0.733
Pain	11 (33%)	14 (23%)	0.637
Burning	4 (12%)	12 (20%)	0.608
Urinate Frequently	16 (48%)	30 (50%)	0.713
Strong Urge	13 (39%)	23 (38%)	0.963
Diagnosed with UTI in past year	1 (5%)	6 (19%)	0.099
Heard of FUDD	12 (36%)	35 (58%)	0.063

Table 3. Factors that affected FUDD use & frequency of use at 3 & 6 months.

	3 Months	6 Months
N	**22**	**26**
Reasons FUDD was not used regularly		
It was messy	1 (4%)	0
I found it difficult to urinate while using the FUDD	1 (4%)	1 (11%)
Toileting facilities were adequate and accessible	8 (35%)	7 (78%)
I did not see how using the FUDD would be beneficial	1 (4%)	1 (11%)
I lost my FUDD	1 (4%)	0
It was difficult to carry around with my gear	0	1 (11%)
It was difficult to place in my trousers	1 (4%)	0
The FUDD was difficult to clean	0	1 (11%)
Factors that influenced FUDD use		
Unsanitary toilet facilities	4 (33%)	10 (59%)
Long distance to toilets	6 (50%)	11 (65%)
I did not want to go outside the barracks to urinate at night	4 (33%)	9 (53%)
The toilets were not private	1 (8%)	5 (29%)
The bathrooms smelled bad	2 (17%)	5 (29%)
Frequency of FUDD use during last 3 mo of deployment		
Used FUDD regularly	12 (55%)	17 (65%)
Did not use FUDD regularly	10 (45%)	9 (35%)
Situations where FUDD was used		
In a military vehicle	4 (17%)	5 (29%)
In my living quarters	7 (30%)	10 (59%)
Outside	8 (35%)	12 (71%)
Inside a clean toilet facility	3 (13%)	1 (6%)
Inside a dirty toilet facility	6 (26%)	7 (41%)
FUDD issues		
Messy/ leaking	3 (13%)	8 (47%)
Difficult to apply in trousers	2 (9%)	2 (12%)
Difficult to remove from trousers	4 (17%)	3 (18%)
Did not experience problems with the FUDD	5 (22%)	5 (29%)
Ability to rinse FUDD after each use)		
Often	10 (83%)	16 (94%)
Never	2 (17%)	1 (6%)
Overall satisfaction with the FUDD		
Satisfied	17 (100%)	22 (100%)
Dissatisfied	0	0
Would recommend the FUDD to other females deploying?		
Yes	22 (100%)	25 (96%)
No	0	1 (4%)
FUDD should be provided to all deploying MW		
Yes	21 (95%)	24 (95%)
No	1 (5%)	1 (5%)

Table 4. Comparison of CG & IG responses at 3 and 6 months.

	3 Months		6 Months	
	Control	FUDD	Control	FUDD
N	7	22	6	26
Urination Symptoms				
Foul smelling urine	0	1 (5%)	2 (33%)	0
Cloudy looking urine	0	2 (9%)	2 (33%)	1 (4%)
Blood in urine	0	0	0	0
Pelvic pain when urinating	2 (27%)	0	2 (33)%	0
Urinating frequently	1 (14%)	1 (5%)	3 (50%)	7
Strong urge to urinate	2 (29%	1 (5%)	2 (33%)	2 (8%)
Did not experience any of these	4 (57%)	18 (82%)	3 (50%)	19
Treatment for Urination Symptoms				
Foul smelling urine	0	0	0	0
Cloudy looking urine	0	0	0	0
Blood in urine	0	0	0	0
Pelvic pain when urinating	1 (33%)	0	0	0
Urinating frequently	1 (33%)	0	0	0
Strong urge to urinate	1 (33%)	0	0	0
Did not seek treatment for these	2 (67%)	4 (100%)	3 (100%)	7
During the last 3 months of deployment, were you unable to work due to urinary infection				
Yes	0	0	0	0
No	3 (100%)	4 (100%)	3 (100%)	7
During the last 3 months of deployment, were you diagnosed with a UTI				
Yes	0	0	0	1 (4%)
No	6 (100%)	22	6 (100%)	25
During last 3 months of deployment, were you treated with antibiotics for a diagnosed UTI?				
Yes	NA	NA	NA	1
No	NA	NA	NA	0
During the last 3 months of deployment, were you treated for dehydration?				
Yes	1 (17%)	0	0	0
No	5 (83%)	22 (100%)	6 (100%)	26
Were you ever in a situation where there were no toilet facilities available?				
Yes	1 (17%)	18 (82%)	4 (67%)	19 (73%)
No	5 (83%)	4 (18%)	2 (33%)	7 (27%)
When there were no toilet facilities available?				
Used FUDD	NA	14 (78%)	1 (25%)	18 (95%)
Held urination until I could get to a	2 (67%)	8 (44%)	2 (50%)	9 (47%)
Found discreet place outside to urinate	2 (67%)	8 (44%)	2 (50%)	8 (42%)
Urinated in a container in an indoor	3 (100%)	2 (11%)	1 (25%)	1 (5%)

Table 5. Comparison of CG and IG responses at 3 and 6 months.

	3 Months		6 Months	
	Control	**FUDD**	**Control**	**FUDD**
N	**7**	**22**	**6**	**26**
Urination Symptoms				
Foul smelling urine	0	1 (5%)	2 (33%)	0
Cloudy looking urine	0	2 (9%)	2 (33%)	1 (4%)
Blood in urine	0	0	0	0
Pelvic pain when urinating	2 (27%)	0	2 (33)%	0
Urinating frequently	1 (14%)	1 (5%)	3 (50%)	7 (27%)
Strong urge to urinate	2 (29%	1 (5%)	2 (33%)	2 (8%)
Did not experience any of these problems	4 (57%)	18 (82%)	3 (50%)	19 (73%)
Treatment for Urination Symptoms				
Foul smelling urine	0	0	0	0
Cloudy looking urine	0	0	0	0
Blood in urine	0	0	0	0
Pelvic pain when urinating	1 (33%)	0	0	0
Urinating frequently	1 (33%)	0	0	0
Strong urge to urinate	1 (33%)	0	0	0
Did not seek treatment for these problems	2 (67%)	4 (100%)	3	7 (100%)
During last 3 months of deployment, were you unable to work due to urinary infection symptoms?				
Yes	0	0	0	0
No	3	4 (100%)	3	7 (100%)
During last 3 months of deployment, DIAGNOSED with UTI?				
Yes	0	0	0	1 (4%)
No	6	22	6	25 (96%)
During last 3 months of deployment, treated with antibiotics when diagnosed with a UTI?				
Yes	NA	NA	NA	1 (100%)
No	NA	NA	NA	0
During last 3 months of deployment, treated for dehydration?				
Yes	1 (17%)	0	0	0
No	5 (83%)	22 (100%)	6 (100%)	26 (100%)
Were you ever in a situation where there were no toilet facilities available?				
Yes	1 (17%)	18 (82%)	4 (67%)	19 (73%)
No	5 (83%)	4 (18%)	2 (33%)	7 (27%)
When there were no toilet facilities available?				
Used FUDD	NA	14 (78%)	1 (25%)	18 (95%)
Held urination until I could get to a toilet	2 (67%)	8 (44%)	2 (50%)	9 (47%)
Found discreet place outside to urinate	2 (67%)	8 (44%)	2 (50%)	8 (42%)
Urinated in a container in an indoor area	3 (100%)	2 (11%)	1 (25%)	1 (5%)

Program Budget Summary Report

Company: The Geneva Foundation
User: etappero@corp.genevausa.org

Period Start Date: 6/1/2012
Period End Date: 5/31/2016

Contract: 10245 - A Female Urinary Diversion Device for Militar
Award Amount: 188,269.00
Total Estimated: 188,269.00
Total Funded: 188,269.00

Contract PoP: 6/1/2011 - 5/31/2016
Customer: TRISERVICE NURSING RESEARCH PROGRAM
Customer Contract ID: HU0001-11-1-TS02
Contract Manager: Robinson, Kathleen

Category	Budget	Period	Cumulative	Commitments	Cumul. + Commit.	Remaining Balance
Direct Expenditures						
Personnel						
Personnel Salary & Wages	62,984.71	62,984.71	62,984.71	0.00	62,984.71	0.00
Fringe Benefits (Burden)	0.00	0.00	0.00	0.00	0.00	0.00
Total Personnel	**62,984.71**	**62,984.71**	**62,984.71**	**0.00**	**0.00**	**0.00**
Non-Personnel						
Equipment	0.00	0.00	0.00	0.00	0.00	0.00
Travel	5,416.25	4,653.25	4,653.25	0.00	4,653.25	763.00
Supplies	9,619.46	9,223.41	9,223.41	0.00	9,223.41	396.05
Other	3,291.47	3,197.68	3,197.68	-4.31	3,193.37	98.10
Consultant	30,900.00	30,900.00	30,900.00	0.00	30,900.00	0.00
Subcontractor Salary & Wages	0.00	0.00	0.00	0.00	0.00	0.00
Subcontractor Other	54,609.11	54,609.11	54,609.11	0.00	54,609.11	0.00
Total Non-Personnel	**103,836.29**	**102,583.45**	**102,583.45**	**-4.31**	**102,579.14**	**1,257.15**
Total Direct Expenditures	**166,821.00**	**165,568.16**	**165,568.16**	**-4.31**	**165,563.85**	**1,257.15**
Indirect Expenditures						
G&A Burden	27,305.00	21,910.57	21,910.57	-2,957.77	18,952.80	8,352.36
Other Indirect Costs	-5,857.17	0.00	0.00	0.00	0.00	-5,857.17
Total Indirect Expenditures	**21,447.83**	**21,910.57**	**21,910.57**	**-2,957.77**	**18,952.80**	**2,495.19**
Total Dir. + Indir. Expenditures	**188,268.83**	**187,478.73**	**187,478.73**	**-2,962.08**	**184,516.65**	**3,752.34**
Fee Amount	0.00	0.00	0.00	0.00	0.00	0.00
Total Expenditures + Fee	**188,268.83**	**187,478.73**	**187,478.73**	**-2,962.08**	**184,516.65**	**3,752.34**

Mentor Statement

The PI and the mentor met onsite at the TSNRP Dissemination Course (31 Aug-4 Sept 2015) and at length discussed the problems surrounding study attrition and small sample size. Additionally, we subsequently contacted the statistical consultant for the grant, Dr. Dale Glaser, to discuss the possibility of any types of statistical comparison that might be undertaken with the intervention and control groups. After lengthy discussion, it was agreed that no valid statistical comparisons could be undertaken and the results of the study would be descriptive in nature only.
Since September 2015, the PI and the mentor had two additional phone conversations about the study.

Several things happened regarding this study that should be noted by TSNRP. First, the IRB applications required for a device that one could purchase at a camping store were extreme. At one point the Womack IRB asked Dr. Steele to procure an IND agreement; it took months of valuable time to resolve this issue. Second, when the PI deployed, she was told that her study would be appropriately managed by the Army Nurse Corps officers who were assigned to the Center for Nursing Science and Clinical Inquiry (CNSCI) at Fort Bragg, NC. The mentor also agreed to check in with these officers to ask about the progress of the study and to offer assistance as needed. The mentor and the consultant telephoned the CNSCI several times and were told about delays in getting the project director site access and orientation. The mentor offered to get involved regarding this issue and volunteered to contact the Deputy Commander for Nursing to politely assist in the process. On multiple occasions, the mentor was told that the CNSCI officers had the situation under control; the mentor's nor the consultant's help were needed. We were clearly not being told the truth and this study suffered greatly because of poor leadership and management within the CNSCI. Due to this experience I recommend that when a PI is deployed, the nurses assigned to manage the study for the PI be expected to sign a statement that they will take responsibility for the study until the PI returns and they will do their best to manage the study effectively, using information from the PI, the mentor, and consultants in the best interest of the study. This study had the potential to be more powerful if it had been executed as written in the grant and if the CNSCI officers would have accepted the help of the consultant and mentor.